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Docket No. BIO-131

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Assaf Govari	Confirmation No.: 8639
Appln. No.	:	09/882,127	
Filed	:	June 15, 2001	
Title	:	MEDICAL DEVICE WITH POSITION SENSOR HAVING ACCURACY AT HIGH TEMPERATURES	
Art Unit	:	3737	
Examiner	:	Ruth S. Smith	

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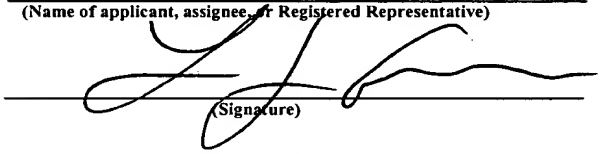
June 1, 2005
(Date of Deposit)

Louis J. Capezzuto
(Name of applicant, assignee, or Registered Representative)



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June 1, 2005
(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

i. Real Party in Interest

Biosense Webster, Inc., a California Corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. **Status of Claims**

Claims 1, 2, 4, 6 – 23, 25 and 27 – 43 are pending in the case. Claims 1, 2, 4, 6 – 23, 25 and 27 – 43 have been finally rejected on December 14, 2004 and this Appeal is taken from these claims.

iv. **Status of Amendments**

An Amendment under 37 CFR § 1.116 had been filed on April 8, 2005 which made minor amendments to the Specification in order to satisfy formal matters raised by the Examiner. This Amendment is believed to have been entered since there are no indications to the contrary in the Advisory Action mailed on April 19, 2005.

v. **Summary of Claimed Subject Matter**

As fully supported in Applicant's Specification, for example, Figs. 1A, 1B and 2 and Page 13, line 12 – Page 14, line 21, Claim 1 of the present invention is directed toward a medical device 80 and position sensor 10 combination having a body 85 of the medical device 80 and a position sensor 10 attached to a portion of the body 85. The position sensor 10 has a core 12 made of a Wiegand effect material, and a winding 14 circumferentially positioned around the core. Page 13, line 24 – Page 14, line 2; Page 15, line 16 – Page 17, line 27.

The position sensor 10 in accordance with Applicant's claimed invention is used for determining position coordinates of the portion of the body 85 of the medical device 80 such that the position sensor 10 maintains accuracy of $\leq$1 mm at temperatures greater than 75°C, i.e. position coordinates of the portion of the medical device body 85 can be successfully determined at an accuracy of $\leq$1 mm while the medical device 80 is operating at very high temperatures, such as temperatures

greater than 75°C. Page 19, lines 3 – 21. See temperature sensitivity test results in Fig. 6. This is particularly important since these novel features and function allow the medical device 80 to be used and its position coordinates accurately tracked (at an accuracy ≤1mm) during a medical procedure that involves extremely high temperatures such as an ablation procedure as indicated in the Specification at Page 32, lines 1 – 10.

Claim 21 of the present invention is directed to a medical device and position sensor combination comprising a medical device 80 having a body 85 and a position sensor 10 attached to a portion of the body 85. Page 13, line 12 – Page 14, line 21and Figs. 1A, 1B and 2. The position sensor 10 has a core 12 made of a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field as indicated at Page 17, lines 9 – 27 and best illustrated in Fig. 5. The position sensor 10 is used for determining position coordinates of the portion of the body 85 of the medical device 80 such that the position sensor 10 maintains accuracy at ≤1 mm at temperatures greater than 75°C as described at Page 19, lines 3 – 21. Again, the significance of this phenomena achieved by these novel features and functions is that the position coordinates of a portion of the medical device 80 can be successfully and accurately tracked at an accuracy of ≤1 mm while the medical device 80 is operated during a medical procedure that involves extremely high temperatures such as an ablation procedure. Page 32, lines 1 – 10 and Fig. 6.

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 1-2, 4, 7-11, 21-23, 25 and 28-32 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in

view of U.S. Patent 5,280,222 (von der Heide et al.) and U.S. Patent 4,538,082 (Hinke et al.) or U.S. Patent 4,639,670 (Normann).

2. Claims 6, 12-18, 20, 27, 33-39 and 41 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of von der Heide et al. and Hinke et al. or Normann as applied to Claims 1, 4, 11, 21, 25 and 32 above, and further in view of U.S. Patent 4,247,601 (Wiegand).

3. Claims 19 and 40 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of von der Heide et al. and Hinke et al. or Normann as applied to Claims 9 and 30 above and further in view of U.S. Patent 4,437,963 (Yeoman).

4. Claims 21, 25, 28-32, 41 and 42 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of European Patent 0348557 (Honkura et al.).

5. Claims 21, 25, 28-32 and 41-43 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of U.S. Patent 6,270,591 (Chiriac et al.).

vii. Argument

1. The rejection of Claims 1-2, 4, 7-11, 21-23, 25 and 28-32 under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of U.S. Patent 5,280,222 (von der Heide et al.) and U.S.

Patent 4,538,082 (Hinke et al.) or U.S. Patent 4,639,670 (Normann) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Turning now to the prior art references (and Applicant's own admissions of the teachings of the prior art) that form the basis of this rejection, the Applicant has admitted the mere fact that the prior art does disclose that a position sensor for a medical device can be a Hall effect sensor. This admission can be found in the Applicant's Specification, particularly on Page 1, Line 20 – Page 2, Line 22.

As noted in the Applicant's Specification, the Hall effect sensor assembly described in U.S. Patent 5,558,091 suffer from problems such as nonlinearities, saturation effects, hysteresis and temperature drifts. Additionally, as described in Applicant's Specification, Page 6, Lines 22-26, until the Applicant's claimed present invention, there have been no position sensors (which include Hall effect sensors) or sensor coils that have outer diameters smaller in size than the diameters of the known sensors described previously and that are capable of achieving performance measures such as maintaining a high degree of accuracy at high temperatures.

Additionally, each of the cited prior art references used in the prior art rejection outlined above are merely general teachings derived from unrelated fields when compared

to the particular field of the Applicant's claimed present invention (the navigated medical device field). Particularly, von der Heide et al. describes an apparatus and method for controlling brushless electric motors and position encoders and indicating the position thereof. Although this reference does relate to Wiegand effect sensors, it is clear that these sensors are used specifically for linear or rotary acting electric motors. Column 1, Lines 15-18, Lines 35-38, and Lines 46-49. Moreover, there is no teaching or suggestion in this reference that Weigand effect material could be used as part of a position sensor together with a medical device for determining position coordinates of a portion of the medical device and for ensuring that the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Hinke et al. describes a high-output magnetic field transducer suitable for use as a contactless ignition signal transducer (for example to replace mechanical breaker points in an ignition system for an externally ignited internal combustion engine) especially for automotive applications. Column 1, Lines 5-14. This reference lacks any teaching or suggestion of a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$ 1mm at temperatures greater than 75°C.

Normann describes a magnetic field sensor comprising Wiegand wires or similar distable magnetic elements that is capable of delivering an individual pulse at a higher energy content than the pulse usually delivered by a single bistable magnetic element and in which the higher pulse energy is produced without a need for a supply of electric power. Column 3, Lines 43-49. Particularly, the magnetic field sensor of Normann is specifically applied to the field of optical fiber links, for example, for use with a light-emitting diode used as a transmitter diode in an optical fiber link. Column 5, Lines 13-16. There is no teaching or suggestion in this reference for using Wiegand effect material as part of position sensor together with a medical device for determining position coordinates of a portion of the medical device wherein the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Moreover, as set fourth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

Since von der Heide et al. (apparatus and method for controlling brushless electric motors and position encoders), Hinke et al. (replacement of mechanical breaker points in an ignition system for an externally ignited internal combustion engine especially useful for automotive applications) and Normann (optical fiber links such as those used with a light-emitting diode as a transmitter diode in an optical fiber link) are so far removed from Applicant's field of endeavor for Applicant's present invention, i.e. the navigated medical device field, the skilled artisan in this medical device field would be entirely discouraged from following the path set out in the teachings from each of these references. Accordingly, each of these cited prior art references clearly teach away from Applicant's present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore*

and Associates, Inc., v. Garlock, Inc., 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed

not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Accordingly, based on the significant shortcomings in the teachings of each of the references as well as their clearly divergent fields of endeavor (when compared to Applicant's field of navigated medical devices) forming the basis for this rejection, there is simply no motivation for one of ordinary skill in this field to combine these references in the manner suggested by the Examiner. Moreover, even if these references are to be combined in the manner suggested (to include in combination with Applicant's limited admission of the use of Hall effect sensors as position sensors), this combination of references completely fails to achieve the novel combination of features and function of the Applicant's claimed present invention, namely, a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material (or a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field) and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Accordingly, since these references fail to show any teaching or motivation to combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and as a classic example of hindsight. Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

2. The rejection of Claims 6, 12-18, 20, 27, 33-39 and 41 under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of von der Heide et al. and Hinke et al. or Normann as applied to Claims 1, 4, 11, 21, 25 and 32 above, and further in view of U.S. Patent

4,247,601 (Wiegand) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

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Hinke et al. describes a high-output magnetic field transducer suitable for use as a contactless ignition signal transducer (for example to replace mechanical breaker points in an ignition system for an externally ignited internal combustion engine) especially for automotive applications. Column 1, Lines 5-14. This reference lacks any teaching or suggestion of a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$ 1mm at temperatures greater than 75°C.

Normann describes a magnetic field sensor comprising Wiegand wires or similar distable magnetic elements that is capable of delivering an individual pulse at a higher energy content than the pulse usually delivered by a single bistable magnetic element and in which the higher pulse energy is produced without a need for a supply of electric power. Column 3, Lines 43-49. Particularly, the magnetic field sensor of Normann is specifically applied to the field of optical fiber links, for example, for use with a light-emitting diode used as a transmitter diode in an optical fiber link. Column 5, Lines 13-16. There is no teaching or suggestion in this reference for using Wiegand effect material as part of position sensor together with a medical device for determining position coordinates of a portion of

the medical device wherein the position sensor maintains accuracy of ≤1mm at temperatures greater than 75°C.

The Wiegand prior art reference describes a switchable magnetic device made of Wiegand wire for use in an improved switching device in order to respond to an external magnetic field to produce a pulse having improved signal to noise ratio and a larger peak amplitude. Column 1, Lines 61-65. Outside of this very general teaching, no description, suggestion or inference can be found in this reference that this material could be used as part of a position sensor for a medical device for determining position coordinates of the medical device for maintaining accuracy of ≤1mm at temperatures greater than 75°C.

As set fourth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

Since von der Heide et al. (apparatus and method for controlling brushless electric motors and position encoders), Hinke et al. (replacement of mechanical breaker points in an ignition system for an externally ignited internal combustion engine especially useful for automotive applications), Normann (optical fiber links such as those used with a light-emitting diode as a transmitter diode in an optical fiber link) and Weigand (general teaching for using a material capable of producing a pulse having improved signal to noise ratio and a larger peak amplitude) are so far removed from Applicant's field of endeavor for Applicant's present invention, i.e. the navigated medical device field, the skilled artisan in this medical device field would be entirely discouraged from following the path set out in the teachings from each of these references. Accordingly, each of these cited prior art references clearly teach away from Applicant's present invention.

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USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Accordingly, based on the significant shortcomings in the teachings of each of the references as well as their clearly divergent fields of endeavor (when compared to Applicant's field of navigated medical devices) forming the basis for this rejection, there is simply no motivation for one of ordinary skill in this field to combine these references in the manner suggested by the Examiner. Moreover, even if these references are to be combined in the manner suggested (to include in combination with Applicant's limited admission of the use of Hall effect sensors as position sensors), this combination of references completely fails to achieve the novel combination of features and function of the Applicant's claimed present invention, namely, a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material (or a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field) and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$1 mm at temperatures greater than 75°C.

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disclosure is being improperly used as a blue print and as a classic example of hindsight. Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

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Additionally, each of the cited prior art references used in the prior art rejection outlined above are merely general teachings derived from unrelated fields when compared to the particular field of the Applicant's claimed present invention (the navigated medical device field). Particularly, von der Heide et al. describes an apparatus and method for controlling brushless electric motors and position encoders and indicating the position thereof. Although this reference does relate to Wiegand effect sensors, it is clear that these sensors are used specifically for linear or rotary acting electric motors. Column 1, Lines 15-18, Lines 35-38, and Lines 46-49. Moreover, there is no teaching or suggestion in this reference that Weigand effect material could be used as part of a position sensor together with a medical device for determining position coordinates of a portion of the medical device and for ensuring that the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Hinke et al. describes a high-output magnetic field transducer suitable for use as a contactless ignition signal transducer (for example to replace mechanical breaker points in an ignition system for an externally ignited internal combustion engine) especially for automotive applications. Column 1, Lines 5-14. This reference lacks any teaching or suggestion of a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$ 1mm at temperatures greater than 75°C.

Normann describes a magnetic field sensor comprising Wiegand wires or similar distable magnetic elements that is capable of delivering an individual pulse at a higher energy content than the pulse usually delivered by a single bistable magnetic element and in which the higher pulse energy is produced without a need for a supply of electric power. Column 3, Lines 43-49. Particularly, the magnetic field sensor of Normann is specifically applied to the field of optical fiber links, for example, for use with a light-emitting diode used as a transmitter diode in an optical fiber link. Column 5, Lines 13-16. There is no teaching or suggestion in this reference for using Wiegand effect material as part of position sensor together with a medical device for determining position coordinates of a portion of the medical device wherein the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Yeoman describes an apparatus for electrolyzing water. Although the Yeoman device utilizes Wiegand wire, it is clear that this device is directed to specifically to methods and apparatus for the electrolysis of water only. Column 1, Lines 35-42. There is nothing that can be found in this reference that would ever lead of one of ordinary skill to arrive at a position sensor and medical device combination wherein the position sensor and Wiegand effect material to determine position coordinates of a portion of the medical device so that the position sensor can maintain accuracy of $\leq$1mm at temperatures greater than 75°C.

Moreover, as set fourth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

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Since von der Heide et al. (apparatus and method for controlling brushless electric motors and position encoders), Hinke et al. (replacement of mechanical breaker points in an ignition system for an externally ignited internal combustion engine especially useful for automotive applications), Normann (optical fiber links such as those used with a light-

emitting diode as a transmitter diode in an optical fiber link) and Yeoman (apparatus for electrolyzing water that happens to use Weigand wire) are so far removed from Applicant's field of endeavor for Applicant's present invention, i.e. the navigated medical device field, the skilled artisan in this medical device field would be entirely discouraged from following the path set out in the teachings from each of these references. Accordingly, each of these cited prior art references clearly teach away from Applicant's present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . .

the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Accordingly, based on the significant shortcomings in the teachings of each of the references as well as their clearly divergent fields of endeavor (when compared to Applicant's field of navigated medical devices) forming the basis for this rejection, there is simply no motivation for one of ordinary skill in this field to combine these references in the manner suggested by the Examiner. Moreover, even if these references are to be combined in the manner suggested (to include in combination with Applicant's limited admission of the use of Hall effect sensors as position sensors), this combination of references completely fails to achieve the novel combination of features and function of the Applicant's claimed present invention, namely, a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material (or a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a

substantially uniform voltage pulse upon an application of an external field) and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Accordingly, since these references fail to show any teaching or motivation to combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and as a classic example of hindsight. Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

4. The rejection of Claims 21, 25, 28-32, 41 and 42 under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of European Patent 0348557 (Honkura et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Turning now to the cited prior art reference of this rejection (and Applicant's own admissions of the teachings of the prior art) that form the basis of this rejection, the Applicant has admitted the mere fact that the prior art does disclose that a position sensor for a medical device can be a Hall effect sensor. This admission can be found in the Applicant's Specification, particularly on Page 1, Line 20 – Page 2, Line 22.

As noted in the Applicant's Specification, the Hall effect sensor assembly described in U.S. Patent 5,558,091 suffer from problems such as nonlinearities, saturation effects, hysteresis and temperature drifts. Additionally, as described in Applicant's Specification, Page 6, Lines 22-26, until the Applicant's claimed present invention, there have been no position sensors (which include Hall effect sensors) or sensor coils that have outer diameters smaller in size than the diameters of the known sensors described previously and that are capable of achieving performance measures such as maintaining a high degree of accuracy at high temperatures.

Additionally, this prior art reference (Honkura et al.) used in the prior art rejection outlined above contains merely general teachings derived from an unrelated field when compared to the particular field of the Applicant's claimed present invention (the navigated medical device field). Particularly, Honkura describes a soft magnetic stainless steel having good cold forge ability and merely mentions that this particular soft magnetic stainless steel can be used in association with magnetic sensors. Column 1, Lines 1-8. Nothing in this reference teaches, suggests or even infers the use of a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field wherein this material is used as part of a position sensor for a medical device for determining position coordinates of the medical device and maintaining its accuracy of $\leq$1mm at temperatures greater than 75°C.

Moreover, as set fourth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

Since Honkura et al. (soft magnetic stainless steel having good cold forge ability with a brief mention that this particular soft magnetic stainless steel can be used in association with magnetic sensors) is so far removed from Applicant's field of endeavor for Applicant's present invention, i.e. the navigated medical device field, the skilled artisan in this medical device field would be entirely discouraged from following the path set out in the teachings from this reference. Accordingly, the Honkura et al. reference clearly teaches away from Applicant's present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or

motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Accordingly, based on the significant shortcomings in the teachings of Honkura et al. as well as the Honkura et al. reference's clearly divergent field of endeavor (when compared to Applicant's field of navigated medical devices) forming the basis for this rejection, there is simply no motivation for one of ordinary skill in this field to combine this reference together with Applicant's own admission of the prior art in the manner suggested by the Examiner. Moreover, even if this reference is to be combined in the manner

suggested (to include in combination with Applicant's limited admission of the use of Hall effect sensors as position sensors), this combination completely fails to achieve the novel combination of features and function of the Applicant's claimed present invention, namely, a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material (or a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field) and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Accordingly, Honkura et al. fails to show any teaching or motivation to combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and as a classic example of hindsight. Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

5. The rejection of Claims 21, 25, 28-32 and 41-43 under 35 U.S.C. § 103(a) as being unpatentable over Applicant's admission of the prior art in view of U.S. Patent 6,270,591 (Chiriac et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of

the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Turning now to the cited prior art reference of this rejection (and Applicant's own admissions of the teachings of the prior art) that form the basis of this rejection, the Applicant has admitted the mere fact that the prior art does disclose that a position sensor for a medical device can be a Hall effect sensor. This admission can be found in the Applicant's Specification, particularly on Page 1, Line 20 – Page 2, Line 22.

As noted in the Applicant's Specification, the Hall effect sensor assembly described in U.S. Patent 5,558,091 suffer from problems such as nonlinearities, saturation effects, hysteresis and temperature drifts. Additionally, as described in Applicant's Specification, Page 6, Lines 22-26, until the Applicant's claimed present invention, there have been no position sensors (which include Hall effect sensors) or sensor coils that have outer diameters smaller in size than the diameters of the known sensors described previously and that are capable of achieving performance measures such as maintaining a high degree of accuracy at high temperatures.

Chiriac et al. describes amorphous and nanocrystalline glass-covered wires for applications in electrotechnics and electronics. Column 1, Lines 4-7. This reference lacks any teaching that either describes, suggests or infers a position sensor having a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field wherein this material is used in combination with a medical device wherein the position sensor is used to determine position coordinates of the medical device while maintaining accuracy of $\leq$1mm at temperatures greater than 75°C.

Moreover, as set fourth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

Since Chiriac et al. contains completely unrelated teachings as well as merely general teachings derived from an unrelated field when compared to the particular field of the Applicant's claimed present invention (the navigated medical device field), i.e. Chiriac et al. is so far removed from Applicant's field of endeavor for Applicant's present invention (the navigated medical device field), the skilled artisan in this medical device field would be entirely discouraged from following the path set out in the teachings from this reference. Accordingly, Chiriac et al. clearly teaches away from Applicant's present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp,* 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

> [t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is

rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Accordingly, based on the significant shortcomings in the teachings of Chiriac et al. as well as the Chiriac et al. reference's clearly divergent field of endeavor (when compared to Applicant's field of navigated medical devices) forming the basis for this rejection, there is simply no motivation for one of ordinary skill in this field to combine this reference together with Applicant's own admission of the prior art in the manner suggested by the

Examiner. Moreover, even if this reference is to be combined in the manner suggested (to include in combination with Applicant's limited admission of the use of Hall effect sensors as position sensors), this combination completely fails to achieve the novel combination of features and function of the Applicant's claimed present invention, namely, a medical device and position sensor combination wherein the position sensor has a core of Weigand effect material (or a high permeable material such as a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field) and a winding so that position coordinates of a portion of the medical device can be determined while the position sensor maintains accuracy of $\leq$1mm at temperatures greater than 75°C.

Thus, since Chiriac et al. fails to show any teaching or motivation to combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and as a classic example of hindsight. Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

Respectfully submitted,

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viii. Claims Appendix

Claim 1. A medical device and position sensor combination comprising:

(a) a medical device having a body;

(b) a position sensor attached to a portion of the body, the position sensor having a core made of a Wiegand effect material, and a winding circumferentially positioned around the core, the position sensor being used for determining position coordinates of the portion of the body of the medical device, the position sensor maintaining accuracy of $\leq$1 mm at temperatures greater than 75°C.

Claim 2. The combination according to Claim 1, wherein the winding is attached to the core.

Claim 4. The combination according to Claim 1, wherein the position sensor is also used to determine orientation coordinates of the portion of the body of the medical device.

Claim 6. The combination according to Claim 1, wherein the position sensor maintains accuracy of $\leq$1 mm at temperatures at approximately 80°C.

Claim 7. The combination according to Claim 1, wherein the core has an outer diameter less than approximately 0.3mm.

Claim 8. The combination according to Claim 7, wherein the core has an outer diameter of about 0.25 mm.

Claim 9.The combination according to Claim 8, wherein the winding is attached to the core.

Claim 10. The combination according to Claim 9, wherein a combination of the core and the winding has an outer diameter less than approximately 0.5 mm.

Claim 11. The combination according to Claim 10, wherein the combination of the core and the winding have an outer diameter of about 0.4 mm.

Claim 12. The combination according to Claim 11, wherein the material of the core comprises cobalt.

Claim 13. The combination according to Claim 12, wherein the material of the core further comprises vanadium.

Claim 14. The combination according to Claim 13, wherein the material of the core further comprises iron.

Claim 15. The combination according to Claim 14, wherein the material of the core comprises approximately 20%-80% cobalt.

Claim 16. The combination according to Claim 14, wherein the material of the core comprises approximately 2%-20% vanadium.

Claim 17. The combination according to Claim 14, wherein the material of the core comprises approximately 25%-50% iron.

Claim 18. The combination according to Claim 14, wherein the material of the core comprises approximately 52% cobalt, 10% vanadium and 38% iron.

Claim 19. The combination according to Claim 9, wherein the winding is made of copper.

Claim 20. The combination according to Claim 4, wherein the position sensor has an accuracy within approximately 0.5 mm.

Claim 21. A medical device and position sensor combination comprising:

(a) a medical device having a body;

(b) a position sensor attached to a portion of the body, the position sensor having a core made of a high permeable material, the material being a magnetic material that produces a magnetic field that switches polarity and causes a substantially uniform voltage pulse upon an application of an external field, the position sensor being used for determining position coordinates of the portion of the body of the medical device, the position sensor maintaining accuracy at $\leq$1 mm at temperatures greater than 75°C.

Claim 22. The combination according to Claim 21, wherein the position sensor further includes a winding positioned around the core.

Claim 23. The combination according to Claim 21, wherein the winding is attached to the core.

Claim 25. The combination according to Claim 21, wherein the position sensor is also used to determine orientation coordinates of the portion of the body of the medical device.

Claim 27. The combination according to Claim 21, wherein the position sensor maintains accuracy at $\leq$1 mm at temperatures at approximately 80°C.

Claim 28. The combination according to Claim 21, wherein the core has an outer diameter less than approximately 0.3mm.

Claim 29. The combination according to Claim 28, wherein the core has an outer diameter of about 0.25 mm.

Claim 30. The combination according to Claim 29, wherein the winding is made of wire.

Claim 31. The combination according to Claim 30, wherein a combination of the core and the winding has an outer diameter less than approximately 0.5 mm.

Claim 32. The combination according to Claim 31, wherein the combination of the core and the winding have an outer diameter of about 0.4 mm.

Claim 33. The combination according to Claim 32, wherein the material of the core comprises cobalt.

Claim 34. The combination according to Claim 33, wherein the material of the core further comprises vanadium.

Claim 35. The combination according to Claim 34, wherein the material of the core further comprises iron.

Claim 36. The combination according to Claim 35, wherein the material of the core comprises approximately 20%-80% cobalt.

Claim 37. The combination according to Claim 35, wherein the material of the core comprises approximately 2%-20% vanadium.

Claim 38. The combination according to Claim 35, wherein the material of the core comprises approximately 25%-50% iron.

Claim 39. The combination according to Claim 35, wherein the material of the core comprises approximately 52% cobalt, 10% vanadium and 38% iron.

Claim 40. The combination according to Claim 30, wherein the wire winding is made of copper.

Claim 41. The combination according to Claim 25, wherein the position sensor has an accuracy within approximately 0.5 mm.

Claim 42. The combination according to Claim 21 wherein the material of the core comprises a copper, nickel and iron alloy (CuNiFe).

Claim 43. The combination according to Claim 21, wherein the material of the core comprises an iron, chrome and cobalt alloy.

ix. Evidence Appendix

Not Applicable.

x. **Related Proceedings Appendix**

Not Applicable.